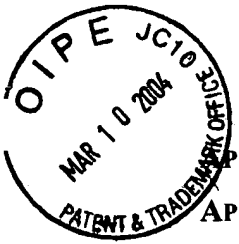


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Date of Deposit: March 10, 2004

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Attorney Docket No. 24348-502



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**APPLICANT(S):** Ben-Sasson *et al.*  
**APPLICATION NO:** 10/664,989 **EXAMINER:** Not yet assigned  
**FILING DATE:** September 17, 2003 **ART UNIT:** 1615  
**FOR:** COMPOSITIONS CAPABLE OF FACILITATING PENETRATION ACROSS A BIOLOGICAL BARRIER

**MAIL STOP IDS**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL LETTER**

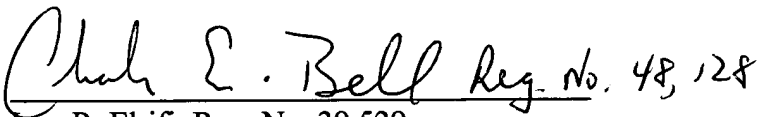
Transmitted herewith for filing in the present application are the following documents:

1. Information Disclosure Statement (2 pages), in duplicate;
2. Modified Form 1449/PTO (2 pages), in duplicate;
3. Copies of Cited References: A1; C1-17; and
4. Return Postcard.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 542-6000, Boston, Massachusetts.

The Commissioner is authorized to charge any fees that may be due, or to credit any overpayment, to the undersigned's account, Deposit Account No. 50-0311 Ref. No. 24348-502. A duplicate copy of this transmittal letter is enclosed herewith.

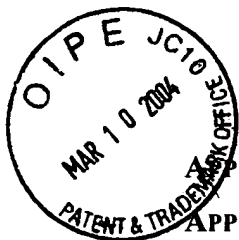
Respectfully submitted,

*for:*  *Reg. No. 48,128*

Ivor R. Elrifi, Reg. No. 39,529  
Christina V. Karnakis, Reg. No. 45,899  
Attorneys for Applicants  
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Date: March 10, 2004



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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**INFORMATION DISCLOSURE STATEMENT**

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants hereby make of record the documents listed on the attached modified Form PTO-1449, as well as copies of the listed documents.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action based on the merits in the above-identified case. Accordingly, no fee or certification is believed required.

It is respectfully requested that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims, and sign the enclosed form PTO-1449 to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.

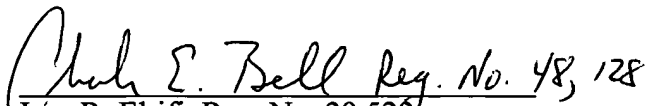
By submitting this Supplemental Information Disclosure Statement, the Applicants make no representation that: (1) a search has been performed, of the extent of any search performed, or that more relevant information does not exist; (2) the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b); and (3) the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

APPLICANT: Ben-Sasson, et al.  
U.S.S.N.: 10/664,989

Notwithstanding any statements by the Applicants, the Examiner is urged to form his/her own conclusion regarding the relevance of the cited information. An early and favorable action is hereby requested.

Please charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No.: 24348-502.

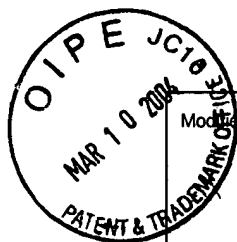
Respectfully submitted,

for:  Reg. No. 48,128  
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Date: March 10, 2004

TRA 1894639v1

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Modified Form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

PTO/SB (12-97)  
Approved for use through 9/30/00. OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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<b>Application Number</b>	10/664,989
<b>Filing Date</b>	September 17, 2003
<b>First Named Inventor</b>	Ben-Sasson
<b>Group Art Unit</b>	1615
<b>Examiner Name</b>	Not Yet Assigned
<b>Attorney Docket Number</b>	24348-502

**U.S. PATENT DOCUMENTS**

Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	A1	5,827,534	10/27/98	Fasano	424	451	

**FOREIGN PATENT DOCUMENTS**

Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C1	Armstrong, W.M., <i>Physiol. Gastrointest. Tract</i> , 2 <sup>nd</sup> Ed., Johnson, ed., Raven Press, New York, ppg. 1251-1265 (1987).
	C2	Bernkop-Schnurch, et al., <i>J. Control. Release</i> , 52:1-16 (1998).
	C3	Citi, S., <i>Cell Biol.</i> , 117:169-178 (1992).
	C4	Fasano, et al., <i>Proc. Nat. Acad. Sci. USA</i> , 88:5242-5246 (1991).
	C5	Fiorentini, et al., <i>Toxicon</i> , 29(6):543-567 (1991).
	C6	Fox, J., <i>Curr. Opin. Pharmacol.</i> , 2:338-344 (2002).
	C7	Gumbiner, <i>Am. J. Physiol (Cell Physiol. 22)</i> , 253:C749-C758 (1987).
	C8	Hecht, et al., <i>J. Clin. Invest.</i> , 82(5):1516-1524 (1988).
	C9	Jackson, <i>Physiol. Gastrointest. Tract</i> , 2 <sup>nd</sup> Ed., Johnson, ed., Raven Press, New York, Chapter 59:1597-1621 (1987).
	C10	Madara, <i>J. Clin. Invest.</i> , 83:1089-1094 (1989).
	C11	Rojas, et al., <i>Nat. Biotechnol.</i> , 16(4):370-375 (1998).
	C12	Schilfgaarde, et al., <i>Infect. And Immun.</i> , 68(8):4616-4623 (2000).
	C13	Schwarze, et al., <i>Science</i> , 285:1569-1572 (1999).
	C14	Toth, I., <i>J. Drug Targeting</i> , 2:217-239 (1994).
	C15	Wang, et al., <i>Am. J. Respir. Cell Mol. Biol.</i> , 22:129-138 (2000).

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C16	Yowell, et al., <i>Cancer Treat. Rev.</i> , 28(Suppl. A):3-6 (2002).
	C17	Zelphati, et al., <i>J. Biol. Chem.</i> , 276(37):35103-35110 (2001).

A copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_\_\_\_, filed \_\_\_\_\_, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.

TRA 1874691v1